

REMARKS

Claims 26, 29, 30, and 33-39 are pending. The specification has been amended to incorporate the current address of the ATCC and to insert ATCC accession numbers for deposited bacterial strains. Claim 25 was cancelled, claim 26 has been amended to insert ATCC designation numbers, and new claims 36-39 have been added. Support for the new claims can be found in original claim 26 and in the as-filed specification at, *e.g.*, page 37, lines 20-30. No new matter has been added by these amendments.

The 35 U.S.C. § 112, first paragraph rejections

Claim 25 was rejected under 35 U.S.C. § 112, first paragraph, as adding new matter. Claim 25 has been cancelled herein. Thus, this rejection is moot and should be withdrawn.

Claims 26, 29, 30 and 33-35 were rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner indicated that the deposit requirement has not been met. *Bacillus coagulans* strains GBI-20, GBI-30, and GBI-40, have now been deposited with the ATCC under the terms of the Budapest Treaty, and the claims have been amended to recite the ATCC designation numbers. Applicant files herewith a Declaration by Sean Farmer, the inventor of the present invention, stating that the deposited bacterial cell lines are the same bacterial cell lines as described in the present application and in my possession at the time the application was filed and an ATCC receipt/viability statement. As suggested by the Examiner, the specification has been amended herein to incorporate the current address of the ATCC and the accession numbers for the claimed strains. Accordingly, this rejection can now be withdrawn.

The 35 U.S.C. § 102(b) rejections

The Examiner stated in the Office action that the insertion of the new matter into the claims has necessitated the removal of the anticipation rejection of Cavadini et al. (US 5,968,569) and Farmer et al. (WO 98/54982), but that removal of new matter will result in the reinstatement of the art rejections. Claim 25, which the Examiner asserted to contain new matter, has been cancelled herein. Therefore, any reinstatement of the rejection of claim 25 in

view of Cavadini et al. and Farmer et al. is made moot by the cancellation of claim 25. Pending claims 26, 29, 30, and 33-35 require a bacteria that is *Bacillus coagulans* GBI-20, *Bacillus coagulans* GBI-30, *Bacillus coagulans* GBI-40, or a combination thereof, which have now been deposited with the ATCC. Thus, the pending claims are not anticipated by the cited prior art, because Cavadini et al. and Farmer et al. do not teach, implicitly or explicitly, these specific isolated *Bacillus coagulans* strains. Therefore, the cited prior art does not contain all the limitations of the pending claims, as amended herein.

The 35 U.S.C. § 103(a) rejections

Claims 26, 29 30 and 33-35 were rejected for obviousness by Cavadini et al. or Farmer et al. in view of Yanagida et al. and Bergey's Manual. As discussed above, the pending claims have been amended to require the specific ATCC-deposited *Bacillus* strains *Bacillus coagulans* GBI-20 (ATCC Designation Number PTA-6085), *Bacillus coagulans* GBI-30 (ATCC Designation Number PTA-6086), *Bacillus coagulans* GBI-40 (ATCC Designation Number PTA-6087), or a combination thereof. The Examiner admits that neither Cavadini et al. nor Farmer et al. teach these isolated *Bacillus* strains. (See, Office action, page 7). However, the Examiner states that Cavadini et al. teach the use of generic *Bacillus coagulans* and Farmer et al. teach particular *Bacillus coagulans* strains. The Examiner further states that Yanagida et al. and Bergey's Manual teach various characteristics of *Bacillus coagulans* bacteria that can be relied upon for strain characterization. (*Id.*). Further, the Examiner states, "[a]lthough the applicant's strains might be different from the prior art strain ATCC 31284 (WO 98/54982) with respect to some unidentified characteristics, the criticalities of the differences, if any, in the method for administration are not clearly pointed out by applicant on the record." (See, Office action, page 9). Thus, the Examiner concludes that one of ordinary skill in the art at the time the claim invention was made would have had a reasonable expectation of success in inhibiting gastrointestinal infection "because the similar, if not identical, bacteria belonging to the species of *Bacillus coagulans* have been known, taught and/or suggested in the prior art for the same purpose of inhibiting gastrointestinal infection in animals." (See, Office action, page 7).

The pending claims are now directed to methods of inhibiting infections in animals by administration of the *Bacillus coagulans* strains GBI-20 (ATCC Designation Number PTA-6085), GBI-30 (ATCC Designation Number PTA-6086) and GBI-40 (ATCC Designation

Number PTA-6087). These novel strains have specific biological characteristics that confer unexpected advantages in the inhibition of infections over the *Bacillus coagulans* strains taught by the prior art. Specifically, these four strains exhibit lower optimal growth temperatures than the *Bacillus coagulans* strain ATCC 31284. The present application demonstrates that the four novel strains have optimal growth temperatures at 40°C or below, and thus grow optimally at physiological temperatures; in contrast, *Bacillus coagulans* strain ATCC 31284 has an optimal growth temperature of 45°C. (See, e.g., Figure 1). The specification indicates that *Bacillus coagulans* strains having lower optimal growth temperatures (40°C or below) have increased efficacy for use as probiotics. (See, e.g., page 37, lines 10-15). Further, Figures 2-4 demonstrate that two of the novel strains, GBI-20 and GBI-30, have superior growth properties as compared to the *Bacillus coagulans* strain ATCC 31284 when tested in a wide variety of growth media, as measured by tetrazolium reduction. (See page 55, line 15 to page 56, line 29).

Thus, contrary to the Examiner's assertions, the novel *Bacillus coagulans* strains GBI-20, GBI-30 and GBI-40 required by the pending claims are distinct from the *Bacillus coagulans* strains of the cited prior art in several clearly identified characteristics that are of key importance in inhibiting gastrointestinal infections in animals. Thus, neither Cavadini et al. nor Farmer et al. describe or suggest the claimed invention.

The Examiner states that the secondary references Yanagida et al. and Bergey's Manual teach various characteristics of *Bacillus coagulans* that are relied on for strain characterization and taxonomic differentiation. As discussed above, the deposited *Bacillus coagulans* strains of the present invention are distinguished from the *Bacillus coagulans* strains of the prior art based on important biological distinctions, including the ability to grow optimally at physiological temperatures. None of the cited references provide any motivation to make the bacterial strains now required by the claims, much less how to generate those *Bacillus coagulans* strains. Thus, these references would not lead one of ordinary skill in the art to the ATCC-deposited *Bacillus coagulans* strains recited in the pending claims

In view of the foregoing arguments, Applicant respectfully requests withdrawal of this rejection.

CONCLUSION

On the basis of the foregoing amendments and arguments, Applicant respectfully submits that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact either of the undersigned at the telephone number provided below.

Respectfully submitted,



Dated: August 9, 2004

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BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.

To: (Name and Address of Depositor or Attorney)

Ganeden Biotech, Inc.
Attn: Benjamin Gerendash
5940 Pacific Mesa Court
Suite 209
San Diego, CA 92121

Deposited on Behalf of: Ganeden Biotech, Inc./ Sean Farmer

Identification Reference by Depositor:

Bacillus coagulans: GBI-20 -SF
Bacillus coagulans: GBI-30 -SF
Bacillus coagulans: GBI-40 -SF

Patent Deposit Designation

PTA-6085
PTA-6086
PTA-6087

The deposits were accompanied by: a scientific description a proposed taxonomic description indicated above. The deposits were received June 18, 2004 by this International Depository Authority and have been accepted.

AT YOUR REQUEST: X We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested June 25, 2004. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:

Marie Harris
Marie Harris, Patent Specialist, ATCC Patent Depository

Date: July 29, 2004

cc: Mintz Levin

Express Mail Label No.:
Date of Deposit:

Attorney Docket No. 19374-509

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : Farmer
ASSIGNEE : GANEDEN Biotech, Inc.
SERIAL NUMBER : 09/708,870
FILING DATE : November 8, 2000
FOR : Inhibition of Pathogens by Probiotic Bacteria

EXAMINER : Afremova, V.
ART UNIT : 1851

Deleted: Not Yet Assigned

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**STATEMENT OF SEAN FARMER REGARDING BIOLOGICAL
CULTURE DEPOSIT**

I, Sean Farmer, of Miami Beach, Florida, declare and state as follows:

1. I am the sole inventor of the invention claimed in the above-referenced application and am employed by the named assignee, Ganeden BioTech, Inc, Beachwood, Ohio.

2. The following bacterial cell lines were deposited on June 18, 2004, with the American Type Culture Collection (ATCC) of 10801 University Boulevard, Manassas, Va. 20110-2209 USA, an official depository for biological materials in accordance with the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure:

GBI-20 (ATCC Designation Number PTA-6085)
GBI-30 (ATCC Designation Number PTA-6086)
GBI-40 (ATCC Designation Number PTA-6087)

Farmer
09/708,870

3. The bacterial cell lines were deposited after the filing date of patent application U.S. Serial Number 09/708,870 and are the same bacterial cells lines as described in the above-referenced patent application and in my possession at the time the application was filed.

4. The bacterial cell lines were tested by the ATCC, and were confirmed to be viable by the ATCC in a letter send July 29, 2004, a copy of which is filed herewith.

5. In the event that the deposited bacterial cell liens mutate, become nonviable, or be inadvertently destroyed, Applicant will replace the cell lines for at least 30 years from the date of the original deposit, or at least 5 years from the date of the most recent request for release of a sample or for the life of any patent issued on the above-referenced patent application, whichever is longer.

6. The deposit of bacterial cell lines was made under conditions of assurance of (a) ready accessibility thereto by the public if a patent is granted whereby all restrictions to the availability to the public of the cell lines so deposited will be irrevocably removed upon the granting of the patent, and (b) access to the culture will be available during pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. § 1.14 and 35 U.S.C. § 122.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are

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punishable by a fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date

8/6/2004

Sean Farmer

TRA 1942326v1